IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JEREMY OLSEN,

Plaintiff

v.

ALEX AZAR, in his capacity as Secretary of the United States Department of Health and Human Services,

Defendant

Case No. _____

COMPLAINT

JURY TRIAL DEMANDED

1. Plaintiff Mr. Jeremy Olsen brings this action against Defendant Alex Azar, in his official capacity as Secretary of the United States Department of Health and Human Services, to obtain injunctive relief for violation of federal law. Plaintiff makes the following allegations based on the investigation of counsel and on information and on personal knowledge.

I. JURISDICTION

2. This Court has jurisdiction over this action pursuant to 42 U.S.C. § 405(g) and 1395ff. Mr. Olsen is filing suit after a final decision of the Medicare Appeals Council (acting on behalf of the Secretary) denying coverage of his Medicare claim (and, therefore, has exhausted his administrative remedies), the amount-in-controversy is more than $1,600 (42 U.S.C. §§ 1395ff(b)(1)(E)(i) and 1395ff(b)(1)(E)(iii)), and this suit was filed within 60 days (plus extensions) of the Secretary's final decision.

3. Venue is proper in this district pursuant to 42 U.S.C. § 1395ff(b)(2)(C)(iii) because this action is being brought in the District of Columbia.

II. PARTIES

4. Plaintiff Jeremy Olsen is an individual and a resident of the State of Washington. Mr. Olsen is eligible for Medicare on the basis of disability as previously determined by the Secretary.

5. Defendant Alex Azar is sued in his official capacity as the Secretary of Health and Human Services.

III. FACTUAL BACKGROUND

6. Diabetes is a disease in which the body either does not produce any/enough insulin (Type I) or does not properly respond to/regulate blood glucose levels (Type II). As a result, the individual may experience high or low blood glucose levels for a prolonged period of time. High

or low blood glucose levels for long periods lead to heart disease, stroke, kidney failure, ulcers (sometimes resulting in amputation), eye damage (sometimes resulting in blindness), and ultimately death. As of 2015, diabetes was the seventh leading cause of death in the United States.[1] Through 2012, the costs related to diabetes (healthcare and lost productivity) were estimated at $245 billion annually. [2]

7. In addition to monitoring through blood tests (see below), many diabetics feel physical symptoms such as blurred vision, fatigue, hunger, and increased thirst that alert them their blood glucose levels are too high or too low. As a result, the diabetic is able to take corrective action (*e.g.*, drinking orange juice).

8. However, the longer patients live with diabetes, the more they lose sensitivity to out of range glucose levels. Thus, they no longer have any physical sense that their glucose level may be too high or too low, and therefore lose this indication that corrective action must be taken. This is referred to as "hyperglycemic or hypoglycemic unawareness."

9. Further, the blood glucose levels of some diabetics are prone to wild and rapid swings either up or down. For example, in the span of minutes, glucose levels may drop precipitously low and the patient may fall into a diabetic coma that proves fatal. This is referred to as "brittle diabetes."

10. It is estimated that one in 20 individuals with diabetes dies each year in their sleep due to an undetected fatal low blood sugar. This is known as "dead in bed syndrome."[3]

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[1] *See* Centers for Disease Control, National Diabetes Statistics Report, 2017, p. 10.
[2] *Id*.
[3] https://www.diapedia.org/acute-and-chronic-complications-of-diabetes/7105157816/dead-in-bed-syndrome (accessed October 9, 2018).

11. For such individuals, \ effectively monitoring glucose levels requires that blood testing needs to be performed several times a day, even during the night.

A. Glucose Tests

12. Prior to the early 2000's, the most common method for patients to monitor blood glucose levels was by pricking a finger to draw blood, and this method is still used today. The drawn blood is placed on a test strip coated with glucose oxidase. Glucose in the blood and the glucose oxidase on the test strip react and, in doing so, consume oxygen. The oxygen consumption results in a reaction that can be detected, either as an electrical charge that is measured by a glucose meter, or as change in color on the test strip which is correlated with actual blood glucose levels.

13. This method has several disadvantages. First, it requires patients to prick their fingers multiple (*e.g.*, 12) times a day. Further, because some of those times will be when the patient is sleeping, the patient must awake throughout the night and cannot get a full night's sleep. Second, because it is done on relatively long intervals, brittle diabetes patients may suffer an episode between testing periods. Thus, a brittle diabetes patient fully compliant with this testing procedure may still die because the onset of symptoms is so quick, occurring between testing intervals.

B. Continuous Glucose Monitors

14. The disadvantages of finger prick/test strips led researchers to develop continuous glucose monitors which became available starting in the mid-2000s. When using a CGM, a disposable sensor is placed below the skin in the space between tissues (interstitial space) that is filled with fluids going to and from cells. These interstitial fluids contain glucose that has come from the blood and is on the way to the cells. Thus, interstitial glucose is correlated with the glucose in blood itself. Current CGM sensors last for a week and measure glucose levels every

five to seven minutes (*i.e.*, nearly 300 times/day) without requiring patient interaction - including when the patient is sleeping.

15. The output from a CGM sensor is sent, via a transmitter, to a CGM receiver/monitor or even a smart phone/tablet. A CGM transmitter typically lasts for several months. The CGM receiver/monitor or smart phone/tablet monitors the detected glucose levels and reports the results to the patient or to a healthcare provider, and/or triggers an alert. Further, when using a smart phone or tablet, an application on the device can plot glucose trends and perform further analyses.

16. Typically, the CGM is calibrated by finger prick/test strip testing twice a day. Some newer CGM devices eliminate the need for calibration.

17. Accordingly, CGMs offer many advantages over finger prick/test strips. First, they monitor glucose levels much more frequently - meaning that brittle diabetes patients enjoy decreased risk of death from a rapid onset of symptoms. Second, even for non-brittle diabetes patients, the increased monitoring frequency detects changes in glucose levels more quickly, usually before the patient feels physical symptoms, and leads to much finer glucose level control, thereby reducing diabetes related health complications. Third, the monitoring occurs without patient interaction - meaning that patients can sleep through the night and/or not interrupt their regular activities. Fourth, patients are not required to prick themselves as frequently – meaning that they do not suffer from near continuous injuries and sources of infection and discomfort.

18. Fifth, the CGM provides trend information regarding how quickly glucose levels are dropping or rising. The trend information is used by patients for the immediate short term management of their diabetes (*e.g.*, "Do I have time to make it to the lunch meeting or should I pull over now and drink juice?"), and are used by clinicians for the long term management of

diabetes (*e.g.*, the patient is experiencing more frequent lows and extreme fluctuations in warm weather and thus should take higher and more frequent doses of glucose in summer months).

19. Overall, these advantages lead to improved glucose monitoring, increased quality of life, and reduced risk of death or other complications.

20. Moreover, CGMs result in decreased health care costs and improved outcomes. Because complications related to glucose control are reduced/avoided, the overall expense of treating a diabetic patient is reduced. For example, many diabetic patients require ambulance transport to the hospital when they suffer an incident. In 2014, more than 450,000 emergency room visits were the result of hyperglycemic or hypoglycemic incidents among diabetics.[4] These episodes are very expensive and a CGM reduces their frequency. Of course, the ultimate cost is death and CGMs reduce the events that can lead to that result.

C. CGM Cost Coverage

21. Modern CGMs cost approximately $300/month over the course of a year for purchase of the CGM receiver, transmitter, disposable sensors, and test strip supplies for result calibration.

22. The advantages of CGMs over finger pricks/test strips are widely recognized in the health care field. Indeed, CGMs have become the standard of care for treating brittle diabetes. As a result, ~98% of private health care providers cover CGM-related costs,[5] indicating their conclusion that covering the cost of the CGM is the cost-efficient approach, compared to covering the costs of ambulances, emergency room visits, and the other increased health care costs of patients without CGMs.

[4] *See* Centers for Disease Control, National Diabetes Statistics Report, 2017, p. 9.
[5] *See* https://provider.dexcom.com/reimbursement/commercial-reimbursement

23. For many patients, doctors describe a CGM as "life-saving."

24. Inexplicably, Medicare has continued to resist covering CGMs. Except with regard to one CGM system, [6] Medicare deems CGMs "not primarily and customarily used to serve a medical purpose" – contrary to logic and medical opinion – and, therefore, not covered durable medical equipment (DME).

D. Durable Medical Equipment

25. Medicare covers "durable medical equipment." Pursuant to 42 U.S.C. § 1395x(n), "durable medical equipment" is not defined, except by example. One such example is "blood glucose monitors."

26. The Secretary has issued regulations further setting forth a five-part test to determine whether equipment is "durable medical equipment" within the meaning of § 1395x(n) (see 42 C.F.R. § 404.202). Equipment is considered "durable medical equipment" if it:

a) Can withstand repeated use;
b) Has an expected life of at least 3 years;
c) Is primarily and customarily used to serve a medical purpose;
d) Generally is not useful to an individual in the absence of illness or injury; and
e) Is appropriate for use in the home.

E. CMS-1682-R

27. Pursuant to 42 U.S.C. § 1395hh(2):

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

28. The "paragraph (1)" referred to requires "notice and comment" as described in the remainder of 42 U.S.C. § 1395hh.

[6] *See* Food and Drug Administration, Premarket Approval P120005/S041 (December 20, 2016).

29. Without notice and comment, on January 12, 2017, CMS issued Ruling No. CMS-1682-R as CMS' "final opinion and order" with regard to CGM coverage.

30. By its own terms, that Ruling is "binding on all CMS components, on all Department of Health and Human Services components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration …".

31. The Ruling addresses whether CGMs are DME and, therefore, covered within the meaning of 42 U.S.C. § 1395x(n) and 42 CFR § 414.202.

32. As set forth in the Ruling, if a CGM does not completely replace finger prick/test strips, CMS considers the device not "primarily and customarily used to serve a medical purpose." This is so, CMS contends – contrary to the facts – because patients do not "mak[e] diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM[.]" See CMS-1682-R at 6-7. CMS calls these CGM's "non-therapeutic."

33. The Ruling also notes that one CGM that has been FDA approved to completely replace finger pricks/test strips is DME (the Dexcom G5). See CMS-1682-R at 7-10. In particular, the Ruling determines that the receiver/monitor portion of a CGM lasts more than 3 years and, including other factors, that the whole system is DME within the meaning of 42 U.S.C. § 1395x(n) and 42 CFR § 414.202.

34. Both before and after issuance of CMS-1682-R, the Secretary has refused coverage of CGM devices made by Medtronic and Dexcom (other than the Dexcom G5) on the grounds that they are not "primarily and customarily used to serve a medical purpose."

35. Further, as a result of CMS-1682-R, the discretion ALJs previously had to award coverage (even in the face of an alleged LCD) was eliminated. As a result, it is futile to submit

claims for non-Dexcom G5 devices with dates of service after January 12, 2017. Because the ALJs no longer have discretion, those claims must be denied.

36. Without notice and comment, CMS-1682-R was incorporated into LCD L33822 and Policy Article A52464, generally excluding CGMs.

37. Thus, the Ruling substituted the non-statutory/regulatory term "therapeutic" for the previous non-statutory/regulatory term "precautionary" as the criteria/basis for denials.

F. Other Litigation Related to CGMs

38. In general, the Secretary has refused to cover CGMs on the grounds that a CGM is not durable medical equipment. National Coverage Determination (NCD) 280.1. This is so, the Secretary contends, because CGMs are not "primarily and customarily used to serve a medical purpose."

39. Instead, the Secretary contends that a CGM is excluded from coverage as "precautionary" – a non-statutory term. Although there was no national or local coverage determination (NCD/LCD) excluding CGM coverage, a local coverage article (LCA) described CGMs as excluded as "precautionary." LCA A52464.

40. The Secretary's refusal to cover CGMs has been the subject of numerous litigations.

41. As to the Secretary's base position that a CGM is not "primarily and customarily used to serve a medical purpose", that position has been rejected by three district courts.

42. In *Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.), *Bloom v. Azar*, 2018 WL 583111 (D. Vt. January 29, 2018) (Crawford, J.) and *Lewis v. Azar*, 2018 WL 1639687 (D. Mass. April 5, 2018) (Gorton, J.), the district courts found that the Secretary's claim that a CGM is not "primarily and customarily used to serve a medical purpose" was

erroneous, not supported by substantial evidence, and in each case, ordered the Secretary to provide CGM coverage.

43. Further, in the *Whitcomb* case, the court found that the Secretary's position was "arbitrary and capricious" and "unreasonable." Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.) at 14, 12.

44. In addition, all three courts found that the Secretary's position lacked "substantial justification" and awarded reimbursement and attorney's fees to the plaintiffs pursuant to the Equal Access to Justice Act. *See* 5 U.S.C. § 504.

45. Likewise, the Secretary's own Civil Remedies Division concluded that exclusion of CGM coverage on the grounds that a CGM is "precautionary" did not pass the "reasonableness standard." *See* DAB No. CR4596, 2016 WL 2851236 at *18.

IV. Facts Specific to Mr. Olsen

46. Jeremy Olsen is a 41-year old father of three and a journeyman carpenter. In his free time, Mr. Olsen enjoys fixing up old cars, woodworking, and crafts activities.

47. First diagnosed with Type I diabetes at the age of nine (9), Mr. Olsen is a "brittle" diabetic (*i.e.*, his glucose levels are prone to wild and rapid swings). In addition, Mr. Olsen suffers from hypo/hyperglycemic unawareness (*i.e.*, he has no physical sensations – head aches, sweats, etc. – that alert him his glucose levels need to be adjusted). Prior to receiving an insulin pump and a CGM, Mr. Olsen had to be revived at the Emergency Room more than 20 times because of his uncontrolled diabetic condition.

48. To assist with management of his diabetes, Mr. Olsen was fitted with an insulin pump.

49. As a result of his diabetic condition, Mr. Olsen suffered from kidney failure. In 2016, Mr. Olsen had kidney and pancreas transplant surgery. While it was hoped that his pancreas transplant would address Mr. Olsen's diabetes, the transplant did not succeed and Mr. Olsen continues to suffer from diabetes.

50. In 2018, Mr. Olsen was prescribed a Medtronic MiniMed continuous glucose monitor, by his treating physician, for two reasons. First, of course, given his brittle diabetes and hypoglycemic unawareness, traditional finger stick checking was not sufficient to manage Mr. Olsen's diabetes such that he continued to suffer a risk of death and other complications. Second, out of range glucose levels as a result of his diabetes jeopardize Mr. Olsen's transplanted kidney.

51. The Medtronic MiniMed CGM communicates with Mr. Olsen's insulin pump to properly regulate the amount of insulin being dispensed. Since receiving an insulin pump and the CGM which interfaces with it, Mr. Olsen has not had to visit the Emergency Room as a result of his diabetic condition.

V. The Claim at Issue in this Case

52. On March 14, April 18, and June 5, 2018, Mr. Olsen received supplies related to his CGM including sensors, an external transmitter, and waterproof tape.

53. The total cost of these materials was $2,444.00.

54. Mr. Olsen's claim for coverage for these items was rejected on July 13, 2018 on the stated grounds that "Medicare does not pay for this item or service." Thereafter, Mr. Olsen sought redetermination.

55. Mr. Olsen's request for redetermination was denied on October 11, 2018 on the stated grounds that Mr. Olsen's CGM did not meet the definition of "therapeutic" in CMS 1682-R and, therefore, that coverage was barred. Thereafter, Mr. Olsen sought reconsideration.

56. Mr. Olsen's request for reconsideration was denied on December 18, 2018. Rather than alleged non-compliance with CMS-1682-R, Mr. Olsen's request was denied on the grounds that the file did not contain an order for the items at issue. Thereafter, Mr. Olsen filed an appeal that was assigned to ALJ Lambert.

57. After conducting a hearing in which CMS chose not to participate, on March 14, 2019, ALJ Lambert issued a decision (ALJ Appeal No. 1-8237389961) holding that the claims should be covered because: 1) there was a signed order for the items in the file; and 2) the CGM works with the insulin pump, which is covered.

58. Thereafter, CMS appealed ALJ Lambert's decision by "referring" it to the Medicare Appeals Council. In particular, CMS alleged that the ALJ erred by not analyzing whether the Medtronic CGM qualified as "therapeutic" under CMS-1682-R and that the Medtronic CGM did not, in fact, qualify.

59. On July 23, 2019, the Council issued a decision reversing ALJ Lambert's decision and denying coverage. In particular, the Council rejected Mr. Olsen's claim on the grounds that the Medtronic CGM does not qualify as "therapeutic" under CMS-1682-R and is, therefore, not "primarily and customarily used to serve a medical purpose." Accordingly, the Council rejected Mr. Olsen's claim on the grounds that a CGM is not "durable medical equipment."

60. On September 23 and November 25, 2019, the Secretary granted Mr. Olsen's requests for extension to file a federal suit to December 30, 2019. This suit was filed before that date.

VI. CAUSES OF ACTION

COUNT I
Violation of 5 U.S.C. § 706(1)
(unlawfully withheld or unreasonably delayed)

61. Paragraphs 1-60 are incorporated by reference as if fully set forth herein.

62. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

63. Based on the foregoing, Plaintiffs ask the Court to reverse the Secretary's Decisions as unlawfully withheld or unreasonably delayed and unsupported by the evidence, and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT II
Violation of 5 U.S.C § 706(2)(A)
(arbitrary and capricious, abuse of discretion, not in accordance with law)

64. Paragraphs 1-63 are incorporated by reference as if fully set forth herein.

65. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

66. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision as arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law, and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT III
Violation of 5 U.S.C § 706(2)(C)
(in excess of statutory jurisdiction, authority, or
limitations or short of statutory right)

67. Paragraphs 1-66 are incorporated by reference as if fully set forth herein.

68. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

69. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision as in excess of the Secretary's authority and limitations and short of Plaintiff's statutory rights and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT IV
Violation of 5 U.S.C § 706(2)(D)
(without observance of procedure required by law)

70. Paragraphs 1-69 are incorporated by reference as if fully set forth herein.

71. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

72. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision as done without observance of the procedure required by law (*e.g.*, notice and comment required for modification of policy) and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT V

Violation of 5 U.S.C § 706(2)(E)
(not supported by substantial evidence)

73. Paragraphs 1-72 are incorporated by reference as if fully set forth herein.

74. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

75. CGM is recognized nationally and internationally by clinicians, researchers, and payers as a reasonable and medically necessary medical device which is the standard of care for individuals suffering from brittle diabetes.

76. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision as not supported by substantial evidence and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

COUNT VI
Violation of 42 U.S.C § 1395hh
(without observance of regulation promulgation)

77. Paragraphs 1-76 are incorporated by reference as if fully set forth herein.

78. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decision and issue an order finding that a CGM and its related supplies are covered durable medical equipment and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

79. Based on the foregoing, Plaintiff asks the Court to declare that CMS-1682-R issued in violation of 42 U.S.C. § 1395hh, as it is a statement of policy published without a notice/comment period establishing/changing a substantive legal standard governing the scope of

benefits, the payment for services, or the eligibility of individuals to receive services or benefits, reverse the Secretary's Decision and issue an order finding that a CGM and its related supplies are covered durable medical equipment, and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that this Court:

A. Enter an order:

(1) setting aside CMS-1682-R and its determination that CGMs that do not completely replace finger prick/test strips are not DME within the meaning of 42 US.C. § 1395x(n) and 42 CFR § 414.202;

(2) setting aside CMS-1682-R as issued in violation of law;

(3) finding that CGMs (whether they completely replace finger prick/test strips or not) are DME within the meaning of 42 US.C. § 1395x(n) and 42 CFR § 414.202;

(4) directing Defendant to provide coverage for Mr. Olsen's claims and

(5) finding the Secretary's denials of CGM coverage on the grounds that a CGM is not DME are not supported by substantial evidence, are arbitrary and capricious, an abuse of discretion, and not in accordance with the law.

B. Award attorney's fees and costs to Plaintiffs as permitted by law; and

C. Such further and other relief this Court deems appropriate.

Dated: December 23, 2019

Respectfully submitted,

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